

IN THE ATTORNEY DOCKET NUMBER

Please change the Attorney Docket No. to --01997.004700--.

REMARKS

In the Advisory Action of February 14, 2002, the Examiner maintained the rejection of Claims 6, 8 and 12-18 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Initially, in response, Applicants wish to point out that, objectively the present invention does satisfy 35 U.S.C. §101. To violate 101, the claims "must be totally incapable of achieving a useful result." Brooktree Corp. v. Advanced Micro Devices, Inc., 24 USPQ 2d 1401, 1412 (Fed. Cir. 1992). In this regard, Applicants and the Examiner have discussed the Patent Office's Revised Interim Utility Guidelines at 64 Fed. Reg. 71440-42, issued December 21, 1999. According to the Revised Guidelines, a single credible assertion of specific and substantial utility for any claimed invention satisfies the utility requirement. Id at 71441. The Revised Guidelines were promulgated in response to concerns of asserted utilities so insubstantial as not to support patentability, "such as the use of a complex invention as landfill." Id.

According to the Revised Guidelines, the Examiner must establish a *prima facie* showing that is more likely than not one skilled in the art would not consider credible any specific and substantial utility asserted by Applicant. Id at 71442. The *prima facie* showing must contain the following elements:

1. An explanation that clearly sets forth the reasoning used;
2. Support for the factual findings relied upon in reaching this conclusion;

and

3. An evaluation of all relevant evidence of record.

The Revised Guidelines emphasize the importance of documentary evidence establishing one of ordinary skill would disbelieve any utility described in the specification for the invention. A *prima facie* showing should provide scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents to support the factual basis. Id.

There was no such documentary evidence provided by the Examiner in support for his factual findings. Accordingly, Applicants respectfully submit there is no adequate basis for the rejection under Section 101. In any event, it is also clear Applicants do meet their burden of showing a credible, specific and substantial utility.

The nucleotide is a full-length clone that encodes a secreted or transmembrane protein isolated from human epidermoid carcinoma cell line. See WO 98/21328 page 35, lines 12-14. As discussed in the specification, Applicants determined the open reading frame "functioned as a signal sequence at the N-terminal" (Id., lines 21 et seq.) and for that reason too, was determined to be a type-I membrane protein.

On November 27, 2001, Applicants provided the Examiner with a copy of GenBank Accession Number NM-005765 illustrating that the present invention encodes a membrane polypeptide associated with the transmembrane sector of vacuolar ATPase. It is well-understood that ATPases are fundamental to energy transport, acidification and homeostasis, etc.

In response, in the February 14, 2002 Advisory Action, the Examiner acknowledged the utility of the present invention but maintained the rejections under 35 U.S.C. §101 and 112 because

Applicant[s] did not contemplate nor have in possession the utility of association with V-type ATPases for this protein containing transmembrane domains at the time of filing.

Frankly speaking, this statement is not well-understood. That is, the submission of NM-005765 was not made for purposes of first alleging utility de novo but, instead, for the purpose of evidencing that Applicants' timely allegation was correct. In other words, NM-005765 is plainly intended only to corroborate Applicants' statements that the present invention can be utilized, e.g., as markers for tissues in which the corresponding protein is preferentially expressed (see WO 98/21328 at page 63, lines 18-19) and for comparison with endogenous DNA sequences to identify genetic disorders (id at lines 24-25), etc.

Of course, this is entirely appropriate under the Revised Guidelines. As explicitly set forth therein, even if the Examiner, arguendo, establishes a *prima facie* case rebutting Applicants' assertions, Applicants are specifically permitted to utilize evidence, including post-filing evidence, to establish that their previous assertions -- even if unsupported at the time made-- were in fact correct.

This is precisely what Applicants did.

Accordingly, even if for that reason alone, those of ordinary skill necessarily recognize the present invention has a specific and credible utility, and plainly satisfies 35 U.S.C. §101. The Examiner has made nothing documentary of record evidencing the

contrary, and the "support for the factual findings relied upon in reaching the conclusion" do not address all of Applicants assertions, as required by the Revised Guidelines.

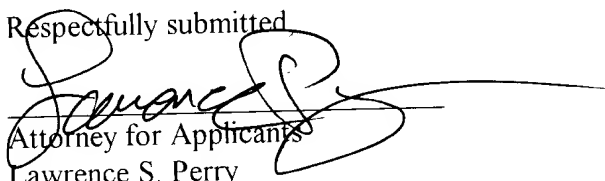
Claims 6, 8 and 12-18 were also rejected under 35 U.S.C. §112 first paragraph. In support of this rejection, the Examiner stated that because the invention is not supported by a substantial asserted utility, one of ordinary skill would not know how to use it. However, as seen explained above, the present invention is supported by a specific and substantial utility.

In view of the above remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 6, 8 and 12-18 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted



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